

RECORD OF THE SUBSTANCE OF THE INTERVIEW

Applicant's appointed representative, attorney Ari M. Bai, conducted a personal interview at the U.S. Patent & Trademark Office with Examiner Rebecca Fritchman and Supervisory Primary Examiner Vicki Kim on January 20 at 2:30 PM Eastern Time for approximately 40 minutes. During the interview, Mr. Bai discussed the Ito reference in order to clarify the structure and operation of the countercurrent chromatography apparatus disclosed in the reference cited by the Examiner. In particular, Mr. Bai explained that based on his discussion with the inventor, Yoichiro Ito, who was also the sole inventor of the Ito reference, the reference failed to teach or suggest that a plate for a countercurrent chromatography apparatus have a plurality of spiral flow channels in which at least one of the plurality of spiral flow channels was in fluid flow communication with another one of the plurality of spiral flow channels. The Examiners agreed with this argument, but wanted to make sure that this particular claim limitation was thoroughly searched during the initial search conducted by the Examiner before making a decision regarding allowing the claims.

Remarks

This responds to the Examiner's Final Office Action mailed on November 16, 2009.

Status of Claims

Claims 1-12, 20, 21 and 25 remain pending in the instant application. Claims 1-12, 20 and 25 have been amended. As such, claims 1 -12, 20, 21, and 25 are pending in the instant application.

Drawings

Figures 1, 2, 3, 4B, 4C and 6 have been amended to more distinctly illustrate certain aspects of the concurrent chromatography apparatus disclosed in the specification as well as correct certain inconsistencies between the drawings and the specification. The Applicant avers that no new matter has been introduced by virtue of the amended drawings and the Examiner is respectfully requested to approve and enter the replacement sheets into the application.

Specification

The Applicant has been amended the application to correct grammatical issues and inconsistencies in the specification. The Applicant avers that no new matter has been introduced into the specification by virtue of these amendments to the specification.

Claim Rejection – 35 USC §103

The Examiner has rejected claims 1-8, 11, 12, 20, 21 and 25 as being obvious over Nunogaki (U.S. Patent No. 4,968,428) in view of Ito (U.S. Patent No. 4,414,108). The Applicant respectfully traverses this rejection.

Applicant respectfully submits that the Office Action did not make out a *prima facie* case of obviousness in connection with any of the above rejections because even if combined, the cited references fail to teach or suggest all of the elements of the

Applicant's claimed invention. The references, when combined, must teach or suggest all of the claim elements.¹

The Examiner asserts that Nunogaki teaches a "counter-current chromatography device using stacked flat rings (plurality of plates) driven in rotation... [and that] [t]hese rings comprise a plurality of cells connected together in a series of ducts engraved on said rings." Although the Examiner admits that Nunogaki ... [does] not teach ... the plates having interleaved spiral flow channels formed therein wherein the flow channels include a first end and a second end wherein the second end of the spiral flow channel is [in] fluid communication with the first end of the second spiral flow channel," the Examiner contends that Ito teaches such a claim limitation.² In particular, the Examiner states that Ito "... teaches ... a flow-through continuous countercurrent chromatography system and more specifically of the plates having interleaved spiral flow channels formed therein wherein the flow channels include a first end and a second end wherein the second end of the first spiral flow channel is fluid communication with the first end of the second spiral flow channel."³ The Examiner concludes that it would have been obvious to one of ordinary skill in the art to combine the stacked chromatography plates of Nunogaki with the interleaved spiral flow channels within the plates of Ito due to the previous problems in the art with coil planet centrifuges."⁴

Independent claim 1, as amended, recites in part "[a] countercurrent chromatography apparatus comprising ... a column assembly comprising a plurality of plates, each of the plurality of plates defining an inlet, an outlet, and a plurality of interleaved spiral channels ... each of the plurality of interleaved spiral flow channels in one of the plurality of plates is in fluid flow communication with another one of the plurality of interleaved spiral flow channels in the same one of the plurality of plates." The Applicant cannot find these claim limitations in the references. In particular, neither Ito nor Nunogaki, alone or in combination, teach or suggest the above claim limitations as discussed below.

¹ M.P.E.P. § 2142 (Citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

² See Office Action at page 2.

³ *Id.*

⁴ *Id.* at Page 3.

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Nunogaki discloses "...a centrifugal counter-current distribution chromatographic apparatus which comprises a motor-driven rotor supported for rotation about a shaft having at least one pocket defined therein, and at least one cassette having a tortuous separation passage defined therein with opposite ends adapted to be connected respectively to a source of fluid samples..."⁵ As noted by the Examiner, Nunogaki fails to disclose "plates having interleaved spiral flow channels formed therein" or that the plate have the "first spiral flow channel [in] fluid communication with ...the second spiral flow channel."⁶

Ito relates to a "flow-through continuous countercurrent extraction system consisting of a coiled tube or spiral coplanar channel revolving around a main axis and rotating around its own axis at the same angular velocity and in the same direction."⁷ The reference discloses several embodiments of the countercurrent extraction system. As illustrated in FIG. 7 and discussed in the detailed description of the Ito specification, one embodiment of the countercurrent extraction system describes that, "...[the] design for a separation bowl 53 [of the countercurrent extraction system] may comprise an aluminum, generally disc-shaped body 60 formed with upstanding concentric inner and outer annular flanges 61 and 62, defining an annular groove 63 therebetween."⁸ Ito continues that "... [a] pair of identical thin-walled spiral channel tubes 64, 64 ... are symmetrically and concentrically arranged in the annular groove 63..."⁹

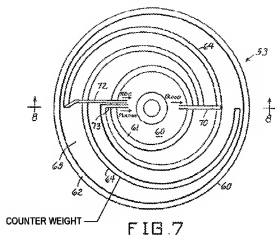
⁵ See Nunogaki at Abstract.

⁶ See Office Action dated November 16, 2009 at page 2.

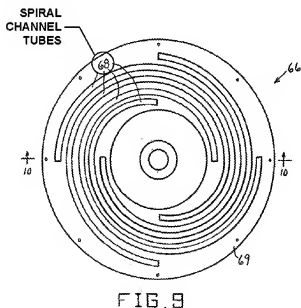
⁷ See Ito at Abstract.

⁸ *Id* at Col. 5, lines 61 - 65.

⁹ *Id* at Col. 5, line 66 – Col. 6, line 1.



Similarly, another embodiment of the separation bowl designated generally as 66 is shown in FIG. 9 of the Ito reference. In that particular embodiment, separation bowl 66 comprises "...an annular aluminum bowl 67 integrally formed with four 90°-spaced concentric identical spiral channels 68."¹⁰



However, neither of the embodiments illustrated in FIGS. 7 and 9 of the Ito reference teach or suggest the claim limitation of independent claim 1 that "each of the interleaved spiral flow channels in one of the plurality of plates is in fluid flow

¹⁰ *Id* at Col. 6, lines 11-14.
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communication with another one of the interleaved spiral flow channels in the same one of the plurality of plates..." of the countercurrent extraction system.¹¹

The Ito reference recites with respect to the embodiment of FIG. 7 that "...during the continuous centrifugal cell separation process the blood sample is admitted via a supply tube 70 to the intermediate portion of a separation cell 64 (or 68). The red blood cells leave via an outlet tube 72 from the large diameter end of the separation channel...[while] [t]he plasma leaves via an outlet tube 73 from the small-diameter end of the channel."¹² However, this operation of the Ito apparatus fails to teach or suggest that an interleaved spiral flow channel of one of the plurality of plates is in fluid flow communication with another interleaved spiral flow channel in the same one of the plurality of plates as presently claimed.

Although the Ito reference discloses identical thin-walled spiral channel tubes 64, 64 of the separation bowl 53 illustrated in FIG. 7, these spiral channel tubes 64 are not in fluid flow communication with each other since one of the spiral channel tubes 64 acts to separate the blood into plasma and red blood cells, while the other spiral channel tube 64 acts only as a counter weight that is required to balance bowl 53 as the chromatography apparatus is rotated. In particular, blood enters the first spiral channel tube 64 through the inlet 70 only and leaves the same spiral flow channel 64 through outlets 72 and 73 for the red blood cells and plasma, respectively. As shown, neither the inlet 70 nor the outlets 72 and 73 are in fluid flow communication with both spiral flow channels 64 since the operation of the countercurrent extraction system of Ito requires only a single spiral flow channel 64 to extract the red blood cells and plasma for blood entering inlet 70 while the other spiral flow channel acts as the counter-weight.

Similarly, the embodiment illustrated in FIG. 9 separates the blood into red blood cells and plasma using only individual spiral flow cells 68 to accomplish the separation and does not teach or suggest that the spiral flow tubes 68 be in fluid flow communication with each other since each of the spiral flow tubes 68 do not communicate with any of the other spiral flow tubes 68. As such, there is no disclosure

¹¹ See Claim 1.

¹² *Id* at Col. 6, lines 20-27.

in the Ito reference that the spiral flow tubes 64 or 68 are in fluid flow communication with other tubes 64 or 68.

Based on the foregoing, there is no teaching or suggestion in either the Ito or Nunogaki references that a plate for a countercurrent chromatography apparatus include a plurality of spiral flow channels wherein one of the plurality of spiral flow channels is in fluid flow communication with another one of the spiral flow channels as presently claimed. Accordingly, the Examiner is respectfully requested to withdraw his rejection of independent claim 1 as being unpatentable over Nunogaki and Ito and indicate the allowance thereof.

Similarly, independent claims 4, 11 and 20 recite substantially the same claim limitation of fluid flow communication being established between one of the interleaved spiral flow channels with another one of the interleaved spiral flow channels. As such, these independent claims are allowable for the same reasons set forth for independent claim 1. In addition, dependent claims 2, 3, 5-10, 12, 21 and 25 are allowable by virtue of their respective dependencies from independent claims 1, 4, 11, and 20.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' representative at (314) 622-6855 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit
Account No. 50-1662.

Respectfully submitted,

POLSINELLI SHUGHART PC

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Dated

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